

REMARKS

Claims 1-18, 20-36, and 73-81 are presented for examination.

Claims 1-18, 20-36, and 73-81 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vigil (U.S. Patent No. 5,336,234) in view of Grayzel (U.S. Patent Publication No. 2002/0010489). However, a person of ordinary skill in the art at the time of Applicants' invention would not have been motivated to combine Vigil and Grayzel to provide a medical device including an inflatable balloon having a first material and a second material (or striped portion) encapsulated by the first material and a cutting element carried by (or attached to) the balloon, as recited in the rejected claims.

Grayzel is directed to a balloon catheter having a balloon with stiffening members that aid in uniform expansion of the balloon at a target site in a lumen in the human body. *See, e.g., ¶ 0013.* Grayzel describes a balloon 14 with multiple stiffening members 16 attached thereto, and notes that stiffening members 16 can be positioned or embedded in the balloon material, as shown in Fig. 5B. *See ¶ 0069.* During use, stiffening members 16 act to focus the expansion force of balloon 14 at occlusions in a lumen contacted by stiffening members 16. *See, e.g., ¶ 0053.*

Vigil is directed to a balloon catheter having oscillatable arthertomes mounted along the outer surface of the balloon. *See, e.g., Col. 1, lines 15-19.* Vigil's Fig. 4 illustrates a catheter 10 that can be used to impart oscillatory motion to arthertomes 19 without relying on the stiffness of thin outer wall 16 of a balloon 12, which can provide a dampening effect. *See, e.g., Col. 4, line 62 through col. 5, line 4.* Arthertomes 19 are attached to a catheter tube 14 by strips 46. *See, e.g., Col. 4, lines 53-55.* During use, oscillatory motion can be transmitted to arthertomes 19 via catheter tube 14. *See, e.g., Col 4, lines 4-13.* Vigil notes that this arrangement can be useful for applications requiring the imposition of more force or higher frequencies in the oscillatory movement motion of arthertomes 19 than is possible in view of the dampening effect of thin wall 16 of balloon 12. *See, e.g., Col. 4, line 62 through col. 5, line 4.*

The Examiner contended in the office action that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Vigil et al.'s device in view of Grayzel et al. by having the strips/reinforcing member encapsulate within the

balloon material." But neither Vigil nor Grayzel provide the requisite suggestion or motivation to make such a modification. As noted above, the arrangement of Vigil's strips 46 permit oscillatory motion to be transmitted to arthertomes 19 without being damped by thin outer wall 16 of balloon 12. In the modified device suggested by the Examiner, oscillatory motion delivered to the arthertomes must be transmitted through and thus damped by the balloon material encapsulating the strips. Not only does Vigil fail to suggest such a modification, Vigil discourages such a modification. Moreover, Vigil makes no mention of problems with non-uniform expansion of the balloon or any other problems allegedly addressed by Grayzel's stiffening members. Therefore, absent the impermissible use of hindsight, a person skilled in the art would not have been motivated to make the modification suggested by the Examiner.

For at least the reasons discussed above, Applicants request reconsideration and withdrawal of the rejection of claims 1-18, 20-36, and 73-81.

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Respectfully submitted,

Date: March 14, 2006


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